[0301] A liquid formulation was prepared. The same can be administered 3 times a day, 20 ml each time, to get a therapeutic dose of 15 mg Neem Leaf CO_2 extract as described herein. The same can be administered 3 times a day, 20 ml each time, to get a therapeutic dose of 150 mg Neem Leaf CO_2 extract as described herein.

[0302] Alternatively, a liposomal water based formulation was prepared using 2 gm of SCO_2 extract as above with 95.6 gm of demineralized water with 2 gm of peppermint oil and 0.2 gm of Rosemary CO_2 extract to obtain 100 gm of mouthwash formulation with minimum additives with standard pharmaceutical grade emulsifier like "Polysorbate 80" 0.2 gm using a high speed homogenizer.

Example 7: Cancer Preventive Effect of a Super Critical CO_2 Neem Extract of Leaf (SCNE)

[0303] Cell Viability Assay:

[0304] Colorectal cancer cells, HCT116 and HT29 as well as normal rat colon cells IEC-6 cells, were plated in 96-well plates, next day the cells were serum starved for 24 hrs and treated with SCNE (0-75 μg/mL) and nimbolide (1-15 μM) for 48 h and 72 h. After treatment, cell viability was measured by MTT [3-(4, 5-Dimethylthiazol-2-yl)-2, 5-Diphenyltetrazolium Bromide] assay (Sigma Aldrich, MO) according to the manufacturer's instructions. Briefly, MTT (5 mg/mL) was added and plates were incubated at 37° C. for 4 h before dimethyl sulfoxide was added to each well. Finally, the absorbance of each well was read at a wavelength of 540 nm using a plate reader (Molecular Devices, Sunnyvale, Calif., USA). The results were expressed as a percentage of surviving cells over non-treated cells.

[0305] The results confirm that the SCNE is non-toxic to normal rat colon cells IEC-6 cells even at higher concentration of 50 μg/mL after 48 hrs (FIG. **14**). The SCNE treated colorectal cancer cells, viz., HCT116 and HT29 exhibits 62% (FIG. **15**) and 44% cell viability (FIG. **16**) respectively at a concentration of 15 μg/mL at the end of 72 hrs and exhibits zero cell viability at a concentration of 40 μg/mL (FIG. **15**) and 75 μg/mL (FIG. **16**) at the end of 72 hrs. The nimbolide treated colorectal cancer cells, viz., HCT116 (FIG. **17**) and HT29 (FIG. **18**) exhibits 80% and 75% cell viability respectively at a concentration of 15 μg/mL at the end of 48 hrs.

[0306] The experiment described herein conclusively confirmed that the super critical CO_2 neem leaf extract (SCNE extract) comprising a combination of nimbolide, nimbin and salinin possess higher therapeutic efficacy than the nimbolide alone.

[0307] Overall, the data suggests that SCNE effectively suppress the growth of human colorectal cancer through induction of apoptosis via pro-inflammatory pathway and NF-kB inhibition.

What is claimed is:

1. A method of treating cancer in a subject, the method comprising:

(a) identifying a subject in need of treatment; and

(b) administering to the subject a composition comprising a therapeutically effective amount of a supercritical CO_2 neem extract (SCNE), wherein the SCNE comprises nimbolide, nimbin and salinin.

2. The method of claim **1**, further comprising a pharmaceutically acceptable excipient.

3. The method of claim **1**, wherein the subject is a human.

4. The method of claim **1**, wherein the pharmaceutically acceptable excipient is selected from the group di-calcium phosphate, distilled water, saline, aqueous glucose solution, alcohol (e.g. ethanol), surfactants, propylene glycol, tween-80 and polyethylene glycol; and oily carriers such as various animal and vegetable oils, white soft paraffin, paraffin, wax, glucose, fructose, sucrose, maltose, yellow dextrin, malt dextrin, white dextrin, aerosol, microcrystalline cellulose, calcium stearate, magnesium stearate, sorbitol, stevioside, corn syrup, lactose, citric acid, tartaric acid, malic acid, succinic acid, lactic acid, L-ascorbic acid, dl-alpha-tocopherol, glycerin, propylene glycol, glycerin fatty ester, poly glycerin fatty ester, sucrose fatty ester, sorbitan fatty ester, propylene glycol fatty ester, *acacia*, carrageenan, casein, gelatin, pectin, agar, vitamin B group, nicotinamide, calcium pantothenate, amino acids, aerated or fumed silica, calcium salts, pigments, flavors and preservatives.

5. The method of claim **1**, wherein the SCNE is administered in a dosage ranging from 50 mg to 1000 mg/day.

6. The method of claim **5**, wherein the amount of SCNE is about 50 mg to 1000 mg/day.

7. The method of claim **1**, wherein the amount of the nimbolide present in the composition is at least 3 mg/g, the amount of the nimbin present in the composition is at least 130 μg/g nimbin; and the amount of the salinin is at least 200 μg/g.

8. The method of claim **1**, wherein the SCNE comprises one or more liminoids.

9. The method of claim **1**, wherein the composition further comprises one or more tocopherols; and sesame oil.

10. The method of claim **9**, wherein the one or more tocopherols are alpha-tocopheraol, gamma-tocopherol, vitamin E or *Rosemarinus officinalis*.

11. The method of claim **1**, wherein the composition further comprises one or more tocopherols; sesame oil; and aerated or fumed silica.

12. The method of claim **1**, wherein the composition is in a form comprising a capsule.

13. The method of claim **1**, wherein the composition is administered orally.

14. The method of claim **12**, wherein the capsule is administered orally two or three times a day.

15. The method of claim **1**, wherein the cancer is a primary or secondary tumor.

16. The method of claim **1**, wherein the cancer is oral cancer or colon cancer.

17. A method of reducing at least one inflammatory cytokine in serum of a subject in need thereof, the method comprising administering to the subject a composition comprising a therapeutically effective amount of a supercritical CO_2 neem extract (SCNE), wherein the SCNE comprises nimbolide, nimbin and salinin.

18. The method of claim **17**, wherein the amount of SCNE is about 50 mg to 75 mg.

19. The method of claim **17**, wherein the SCNE is administered in a dosage ranging from 50 mg to 1000 mg/day.

20. The method of claim **17**, wherein the amount of the nimbolide present in the composition is at least 3 mg/g; the amount of the nimbin present in the composition is at least 130 ng/g; and the amount of the salinin is at least 200 ng/g.

21. The method of claim **17**, wherein the SCNE comprises one or more liminoids.